DEPARTMENT OF HEALTH AND HUMAN SERVICES

Southwest Region 94/238

Food and Drug Administration
Denver District Office
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Denver, Colorado 80225-0087
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December 3, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ron W. Wortley
President
Medron, Inc.
1518 South Gladiola Street
Salt Lake City, UT 84104

Ref # DEN-04-02

Dear Mr. Wortley:

On August 25 through 29, 2003, investigators from the U.S. Food and Drug Administration (FDA), Denver District, conducted an inspection of your establishment located at 1518 South Gladiola Street, Salt Lake City, Utah. Our investigators determined that your firm manufactures a variety of catheters, including intravascular catheters. These products are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h).

As described in the Form FDA-483 left with your firm at the close of the inspection, the investigators found evidence that your medical devices are adulterated under Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with Current Good Manufacturing Practice (CGMP) requirements. CGMP requirements are set forth in FDA's Quality System (QS) regulation, Title 21, Code of Federal Regulations (21 CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria prior to being released for distribution, as required by 21 CFR 820.80 (d).

Specifically, a review of [redacted] Device History Records (DHR) revealed [redacted] lots of product that were released without complete manufacturing/testing results, a Certificate of Conformance, or a Shipping Release form.

2. Failure to establish and maintain procedures which address the identification, documentation, evaluation, segregation, and disposition of nonconforming product, as required by 21 CFR 820.90 (a). Inherent in the evaluation of nonconformance is the assessment of risk and determination of the need for an investigation.

   A review of DHRs, Non-Conforming Materials Reports (NCMR) and Corrective and Preventive Action (CAPA) records revealed instances of: no record of the disposition of nonconforming product, lack of justification for not conducting a failure investigation, lack of CAPA determination, and lack of evaluation/assessment of risk.

3. Failure to establish and maintain procedures for rework, to include re-testing and re-evaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications, as required by 21 CFR 820.90(b)(2). Rework and reevaluation activities, including a determination of any adverse effect from rework upon the product, must be documented in the DHR.

   A review of DHRs and NCMRs that referenced the need for rework did not always include or reference validated procedures to be used to perform the rework. In addition, there was no written requirement to validate rework procedures.

4. Failure to establish and maintain procedures for implementing corrective and preventive action as required by 21 CFR 820.100, including requirements for:
   a. Analyzing quality data, including complaints, product non-conformance and reject forms, and CAPAs, to identify existing and potential causes of nonconforming product, using appropriate statistical methodology, such as trend analysis;
   b. Identifying actions needed to correct and prevent recurrence of non-conforming product, and;
   c. Verifying or validating the corrective and preventive actions, such as [redacted] to ensure that these actions are effective and do not adversely affect the finished device.

5. Failure to conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules.
   Specifically:
   a. Maintenance procedure for the [redacted], calls for [redacted]
   b. Maintenance procedure for the [redacted], calls for [redacted] inspections and [redacted] maintenance;
   c. Maintenance procedure for the [redacted] requires cleaning and lubrication at [redacted] intervals.

   Maintenance records indicate that these schedules are not adhered to, as required by 21 CFR 820.70(g)(2) and 21 CFR 820.72(a).

6. Failure to review, evaluate and investigate all complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications, as required by 21 CFR 820.198(c).

   Specifically, your firm's procedure requires that you perform a [redacted], and [redacted] on the problem, if one exists. A review of your complaint files revealed that these requirements were not being accomplished in all required cases.

7. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization as required by 21 CFR 820.20(a). For example, management with executive responsibility has not maintained an adequate organizational structure to prevent the quality system deviations as identified on the Form FDA-483.

We are in receipt of your correspondence dated June 6, 2003 in response to the FD-483 issued at the conclusion of the inspection. Your response is inadequate in that all numbered items listed above were not addressed. However, we acknowledge that you have implemented some corrective action with respect to Quality Audits, Sampling Plans, Rework Procedures, Quality Trending and Software Validation. Your corrective actions will be evaluated and verified during the next inspection of your firm.

This letter is not intended to provide you with an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment complies with all applicable requirements of federal law and implementing regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA.

Failure to promptly correct these deviations may result in FDA initiating regulatory action without further informal notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. In addition, FDA will not approve an application for premarket approval for Class III devices to which the Quality System regulation deficiencies are reasonably related until the violations are corrected. Also, no requests for FDA export documents will be approved until the violations related to the subject devices have been corrected.

Your response should be sent to William H. Sherer, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087. If you have any questions, please contact Mr. Sherer at (303) 236-3051.

Sincerely,

B. Belinda Collins
District Director